

health to puny, run-down people; that it was a curative, health-building tonic which contained medicine that would be efficacious in the cure, mitigation, treatment, and prevention of diseases and ailments of the liver, kidneys, stomach, spleen, and blood; that it would relieve bladder irritation, would drive out poisonous uric acid, would improve the digestion, would heal the irritated conditions of the stomach and intestinal tract; and that it would be efficacious in the cure, mitigation, treatment, and prevention of aches, pains, and weak run-down conditions, constipation, nervousness, sick headaches, pains under the shoulder, kidney and bladder troubles, indigestion and stomach troubles, misery in the back, sides, and limbs, sore and painful back and head, disturbances of sleep, burning and stinging sensation in the bladder, and frequent urination. The article was not a tonic, diuretic, and alterative, and it would not be efficacious for the purposes represented.

*Laxanodine*, misbranding, Section 502(a), certain statements on the label of the article and in the above-mentioned circulars accompanying the article were false and misleading since they represented and suggested that the article would be efficacious in the treatment of derangements of the liver; that it was a tonic; that it would be efficacious in the cure, mitigation, treatment, and prevention of biliousness, sick headache, acute and chronic indigestion, fevers, jaundice and bowel troubles, constipation, cholera morbus, colics, and teething troubles; that it would be efficacious to restore vigorous health to puny run-down people; that it was a healing medicine prepared from nature's healing herbs; and that it would be efficacious in the cure, mitigation, treatment, and prevention of constipation, sick stomach, nausea and vomiting, hiccups, piles, irritation and soreness of the stomach and bowels, griping and pain in cholera morbus, dysentery and diarrhea, vertigo, colds, flu, stomach, liver and bowel troubles, congestion of the spleen, pain in the side, swelling in the side, high blood pressure, frequent attacks of heart trouble, gastric indigestion, and weak, thin, and emaciated conditions. The article was not a healing medicine prepared from nature's healing herbs, and it would not be efficacious for the purposes represented. Further misbranding, Section 502(f)(2), the article was a laxative, and its labeling failed to bear a warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent and continued use of the article might result in dependence upon laxatives to move the bowels.

*Iron-tone*, misbranding, Section 502(a), certain statements on the label of the article and in the above-mentioned circulars accompanying the article were false and misleading since they represented and suggested that the article would be efficacious as a tonic; that it was a great strength and blood builder; that it would be efficacious in the cure, mitigation, treatment, and prevention of dropsy, tuberculosis, female weakness, suppressed and painful menstruation, and loss of appetite; that it would be efficacious for building pale, weak, puny people of any age; that it would overcome the cause of anemia; that it would be efficacious in the cure, mitigation, treatment, and prevention of anemia caused by malaria, flu, and other weakening diseases; that it would be efficacious in the cure, mitigation, treatment, and prevention of weakness and emaciation, female troubles, piles, including bleeding piles, badly swollen hands and feet, indigestion, and constipation; that it would be efficacious to restore red corpuscles; that it would enrich the blood, would make puny children grow, would strengthen the feeble and aged and would make weak, flabby muscles firm and strong, would color the cheeks with the pink glow of health, would enable women to enjoy better health, and would be efficacious to aid recovery from pneumonia. The article would not be efficacious for the purposes represented.

Further misbranding, Section 502(b)(2), the labels of the articles bore no statement of the quantity of the contents; and, Section 502(e)(2), the labels of the *Laxanodine* and *Iron-tone* failed to bear the common or usual name of each active ingredient.

DISPOSITION: June 4, 1946. A plea of nolo contendere having been entered, the court imposed a fine of \$300 and placed the defendant on probation for a period of 3 years.

1956. Misbranding of Interferin. U. S. v. William H. Kropp (Kropp's Prescription Pharmacy). Plea of guilty. Fine, \$1,000. (F. D. C. No. 17865. Sample No. 17385-H.)

INFORMATION FILED: June 7, 1946, Eastern District of Wisconsin, against William H. Kropp, trading as Kropp's Prescription Pharmacy; charging that the defendant on or about April 19, 1945, received in interstate commerce from

Frank A. Nelson, Chicago, Ill., a number of tubes of *Interferin* which were misbranded, and that the defendant subsequently sold a number of the tubes in violation of Section 301 (c).

**PRODUCT:** Unlabeled collapsible tubes containing an amber-colored paste, known as *Interferin*, intended for introduction into the uterine cavity for the purpose of terminating pregnancy.

**NATURE OF CHARGE:** Misbranding, Section 502 (b) (1) and (2), the product was in package form and failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), it failed to bear adequate directions for use.

**DISPOSITION:** August 14, 1946. A plea of guilty having been entered, the court imposed a fine of \$1,000.

**1957. Misbranding of Chinaroid Rectal Balm. U. S. v. The Knox Co. Plea of nolo contendere. Fine, \$500. (F. D. C. No. 16543. Sample No. 39536-F.)**

**INFORMATION FILED:** October 29, 1945, Western District of New York, against the Knox Co., a corporation, Buffalo, N. Y.

**ALLEGED SHIPMENT:** On or about October 9, 1943, from the State of New York into the State of California.

**PRODUCT:** This product was an ointment in a collapsible tube with a key attachment. The directions called for a "one-quarter turn" of the key. At the start, one-quarter turn would cause an application of ointment containing 0.444 gram of stramonium. As the tube rolled up, the amount would increase until, at the maximum, the one-quarter turn would cause an application of ointment containing 5.056 grams of stramonium.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the labeling of the drug was misleading since it failed to reveal the material fact that the use of the article in accordance with the following directions on the label might have resulted in an overdosage of stramonium, and that an overdosage of stramonium may be dangerous: "Use Twice Daily Attach key to bottom of tube and turn slightly until salve reaches end of applicator and exudes. Insert applicator gently into rectum and turn key, attached to tube, one-quarter turn. This provides the proper dose of Chinaroid. If bleeding exists apply Chinaroid with finger instead of inserting applicator. Repeat morning and night as needed to relieve rectal discomfort. If satisfactory relief is not obtained after using for 2 weeks consult a physician."

Further misbranding, Section 502 (f) (1), the labeling failed to bear adequate directions for use since the directions would provide for the administration of an amount of ointment varying from 0.444 gram to 5.056 grams, which might have resulted in a dangerous overdosage of stramonium; and, Section 502 (f) (2), the label failed to bear adequate warnings against unsafe dosage, or methods or duration of administration or application, since it failed to warn that the dosage should be decreased if blurring of the vision or dryness of the throat should develop, and it failed to warn that if those conditions persisted after decreasing the dosage, use of the article should be discontinued. The labeling failed also to warn against use of the drug in those pathological conditions where its use might have been dangerous to health, since it failed to warn that the article should not be used in case of bleeding, which warning is necessary in the case of drugs intended for introduction into the rectum.

**DISPOSITION:** January 28, 1946. A plea of nolo contendere having been entered on behalf of the defendant, a fine of \$500 was imposed.

**1958. Misbranding of Improved Special Tablets. U. S. v. 34 Bottles of Improved Special Tablets. Default decree of condemnation and destruction. (F. D. C. No. 20277. Sample No. 57040-H.)**

**LIBEL FILED:** June 20, 1946, District of Massachusetts.

**ALLEGED SHIPMENT:** On or about April 30, 1946, by M. A. Williams, Inc., from Woonsocket, R. I.

**PRODUCT:** 34 bottles, each containing 24 *Improved Special Tablets*, at Boston, Mass.

**LABEL, IN PART:** "Improved Special 24 Tablets."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to state why the article was to be used.